

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Application of:

Sherman

Serial No.: 09/829,859

Filed: February 25, 2003

For: A Chest Compression
Device with Electro-
Stimulation

Art Unit: 3762

Examiner: Droesch, K.

RESPONSE TO OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is responsive to the Office Action dated February 25, 2003 in parent application 09/829,859.

Certificate of Mailing (37 CFR 1.10)

I hereby certify that this response (along with any paper referred to as being attached or enclosed) is being deposited in Express Mail using Express Mail Post Office to Addressee with the United States Postal Service on the date shown below in an envelop addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Express Mail No. EV 320597753 US

Date: August 25, 2003

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Remarks

Claims 1 through 3 correspond to claims 1 through 3 in the parent application. Claims 4 and 5 are added in this continuation.

The Office Action objected to claim 2 and rejected claim 1 as being indefinite. The claims presented in this continuation address the objection and the rejection accordingly.

In the previous office actions, the Examiner misapprehended the references and the claims and has also failed to address the most powerful reasons why the claims are patentable. Specifically, the Examiner has failed to address that (1) Lurie, Linder and Freedman do not show electroventilation, they show electrical stimulation of a cough (coughing is not ventilation); (2) Lurie, Linder and Freedman teach away from the claims; and (3) outdated maxims such as "functional equivalents" do not substitute for the mandated test for patentability under Graham v. John Deere. Applicants respectfully request that the Examiner consider and address each argument presented in this response and allow the claims. Applicants address the individual rejections as follows:

The Office Action rejects claim 1 as obvious over Lurie et al., Device and Method for Performing Cardiopulmonary Resuscitation, U.S. Patent 6,234,985 (May 22, 2001) in view of Freedman Jr. et al., Hypothermia-Inducing Resuscitation Unit, U.S. Patent 5,755,756 (May 26, 1998) in view of Linder, Abdominal Binder for Effecting Cough Stimulation, U.S. Patent 5,190,036 (Mar. 2, 1993) in view of Geddes et al., Demand Electroventilator, U.S. Patent 4,827,935 (May 9, 1989) under the assertion that Lurie shows a resuscitation device comprising a chest compression device, an electro stimulation system comprising a pair of ventilation electrodes, an electrical generator, a controller for operating the chest compression device and that the controller is

programmed to operate the system when the device is decompressing the chest; that Freedman shows a transcutaneous electrode to produce a cough in the patient and that Freedman shows that counterpulsation is effected by the controller when the device is decompressing the chest; that Linder shows a pair of counter pulsation electrodes; that Geddes shows the claimed electrical pulse train; and that it would have been obvious to combine these references to (1) effect blood circulation in a patient by adding Freedman to Lurie, (2) substitute the Linder electrodes for the Freedman electrode patch because they are functional equivalents and (3) use the Geddes pulse train to stimulate smooth inhalation in the patient.

The proposed combination does not meet the limitations of claim 1. Claim 1 contains limitations directed to ventilation electrodes, counter-pulsation electrodes and a controller programmed to operate the electrostimulation system when the chest compression device is decompressing the chest. Lurie (the primary reference), Linder and Freedman do not show ventilation electrodes and do not show a controller programmed as claimed. The Office Action statement to the contrary is unfounded and simply not correct. These three references each use electrical stimulation to effect a cough response in the patient. Coughing requires the patient to exhale. Ventilation requires the patient to inhale. For this reason, Lurie and Freedman specifically provide for an additional means for ventilating the patient. Linder and Geddes do not contradict Lurie and Freedman. Thus, the first three references do not teach electrical ventilation.

Geddes does not teach a chest compression device, counter-ventilation or counter-pulsation electrodes. None of the references teach using a controller to operate ventilation electrodes to induce ventilation when a chest compression device is decompressing the chest. Thus, the proposed combination does

not meet the limitations of the claims and the claims are thereby non-obvious.

In addition, the proposed combination does not make sense. The Examiner is proposing a device that is supposed to induce both inhalation and coughing. Given that the rate of compressions/ ventilations is a little over once per second, there is no time for the patient to both cough and inhale during the decompression cycle (less than 0.5 seconds). It is just not possible for the patient to breathe and cough during chest compressions counter-pulsed with ventilations.

In its response to arguments the Office Action states that "Freedman shows the cough-like response is elicited following inhalation and exhalation." This statement does not make sense in the context of the claimed invention. Coughing is still not ventilation. Freedman achieves ventilation through the use of the abdominal cuff and coughing is stimulated after the patient is ventilated. Claim 1 achieves ventilation through the use of electrical stimulation. The fact that Freedman shows that one cannot both cough and breathe at the same time is irrelevant to this patentable difference between claim 1 and the proposed combination. Thus, the proposed combination thus does not meet the claimed limitations and the claims are thereby non-obvious.

With respect to the Office Action response to arguments statement, the Office Action shows that the Examiner has misapprehended Freedman. Freedman discusses using counter-pulsation using abdominal and thoracic cuffs. In the passage cited by the Office Action, electrical stimulation and the abdominal cuff are combined to create a cough response. The timing device is used to control when the patient inhales by controlling the timing of the abdominal and thoracic cuffs, but the electrodes are *only* used to stimulate a coughing response after the patient has breathed. Thus, Freedman adds nothing to

the proposed combination. Accordingly, the proposed combination does not meet the claimed invention and claim 1 is non-obvious.

Lurie, Freedman and Linder each teach away from claim 1. All three references are directed to stimulating only cough responses. One of ordinary skill in the art would not think to combine these references with each other to produce electro-ventilation. Coughing and ventilation are vastly different from each other, and the two responses require different electrical signals (as pointed out by Geddes (col. 1, ll. 53-58)). Given the different physiological responses from different electrical stimulations, there is no reason why one skilled in the art would be motivated to combine these references and there is every reason for one of ordinary skill to not combine the references. One of ordinary skill in the art looking to solve problems in electroventilation would avoid references that teach the opposite response. Since Lurie, Freedman and Linder teach away from claim 1, claim 1 is non-obvious.

In addition, no one of ordinary skill would be motivated to combine Lurie, Freedman and Linder with Geddes. Geddes teaches electroventilation in dogs. The other three references teach methods of electrical induction of coughing. These are opposite responses and no one of ordinary skill would think to combine these references. Thus, no motivation exists to combine the references and claim 1 is thereby non-obvious.

Furthermore, if claim 1 were obvious, then one of ordinary skill in the art would have already patented the claimed invention. Geddes is the only cited reference that has anything to do with electro-ventilation, and Geddes issued almost 15 years ago (May of 1989). Geddes also points out that electroventilation has been known since the late 1800's, over 100 years. Counter-pulsation has also been known for many years. At the same time, there have been hundreds of patents that have issued over the last 15 years that deal with ventilation, chest compressions and CPR.

This is a strong testament to the market and the need for these kinds of devices. Had claim 1 been an obvious combination of existing technology, then it would have already been patented. Since claim 1 is directed to a device that was unknown before Applicants' invention, claim 1 is non-obvious.

In addition, the Office Action rationale for combining Lurie, Linder and Freedman does not meet the mandated test for patentability. The Office Action states that one of ordinary skill could substitute Freedman's electrode patch for Linder's pair of electrodes as functional equivalents that would work equally well to stimulate a cough-like reflex which effects blood circulation. Outdated maxims, such as "functional equivalents" have been replaced by the test put forth in Graham v. John Deere. There must be a motivation to combine the references, and the Office Action has not provided one that is relevant for substituting the proposed electrodes. With respect to stimulating a cough-like reflex to effect blood circulation, this statement is irrelevant to electro-ventilation. The statement that the two electrodes are equivalent in this regard is also without foundation. Thus, the Office Action has failed to state a prima facie obviousness rejection. Accordingly, Applicants request that the rejections be withdrawn and the claims allowed.

The Office Action rejects claims 2 and 3 as obvious over the combination of Lurie, Freedman, Linder and Barkalow et al., Cardiopulmonary Resuscitator, Defibrillator and Monitor, U.S. Patent 4,273,114 (Jun. 16, 1981) under the assertion that Lurie shows an electro-stimulation system which, in addition to the assertions made with respect to claim 1, also comprises defibrillation electrodes controlled by a controller; that Freedman teaches a transcutaneous electrode patch to produce a cough-like response in a patient and that Freedman teaches counterpulsion effected by a controller; that Linder teaches pairs of electrodes applied to the abdomen to stimulate coughing; that

Barkalow teaches applying a defibrillation pulse during a compression of the heart; and that it would have been obvious to combine the references to achieve the claimed limitations because of the reasons given above and to provide electrical signals to the defibrillation electrodes at or near the end of compressions caused by the chest compression device to reduce the amount of energy needed to defibrillate a patient.

The proposed combination does not meet the limitations of claims 2 and 3. As described above, Lurie, Linder and Freedman do not show ventilation electrodes. Barkalow does not show electroventilation and adds nothing to the proposed combination in this regard. Since none of the references show the limitations of the claims, claims 2 and 3 are non-obvious.

For similar reasons to those given above, Lurie, Freedman and Linder teach away from claims 2 and 3. No one of ordinary skill would turn to these references to solve problems in electroventilation, since they deal with producing a cough in the patient. Thus, claims 2 and 3 are non-obvious.

In addition, the Office Action has failed to state a prima facie obviousness rejection. As described above, outdated maxims such as "functional equivalents" have been replaced with the mandated test for patentability. Thus, Applicants request that the rejections be withdrawn and the claims allowed.

In its response to arguments, the Office Action stated that the arguments with respect to claims 1 through 3 are moot in view of the new grounds of rejection. This is simply not true. Most of Applicants' arguments are just as relevant and convincing now as before. Applicants respectfully request that the Examiner consider each argument and allow the claims. In the alternative, Applicants request that the Examiner reply to each of Applicants arguments so that Applicants may have an opportunity to respond.

With respect to all of the claims, neither the art nor the Examiner have any reason to believe or predict that the claimed inventions would work, especially in the context of resuscitation during cardiac arrest. For example, Geddes is described as an electroventilator used on live dogs. As explained in Applicants' first office action response, there is no reason to believe that the Geddes ventilator would work on a cardiac arrest victim. In a cardiac arrest victim the lack of blood flow to all the muscles in the body suggests that the respiratory muscles lack sufficient oxygen supply to support electro-stimulated contraction. Thus, one skilled in the art would think that the methods and devices shown in Geddes would not work. Since there is no reason to predict that the claimed inventions would work, the claims are non-obvious regardless of the obviousness of trying any particular claimed combination. Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044 (Fed. Cir. 1988).

Conclusion

This response has addressed all of the Examiner's grounds for rejection. The rejections based on prior art have been traversed. Reconsideration of the rejections and allowance of the claims is requested.

Date: August 25, 2003

By:

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